# **SPECIFICATION**

[Histamine containing Eye Drops for visual identification of Lymphoid Tissue within the tissues of the eye, that are to be sampled/biopsied for further Diagnostic testing]

Applicant Claims Priority on Provisional Application Certification # 60/466,943, Filed on 04/30/2003.

#### Federal Research Statement

[Not applicable to this Invention]

## Background of Invention

- [] 1) Medical Field Application
- [] 2) Adjunct method for collecting tissue for medical diagnostic testing.
- [] 3) Improves visual identification of lymphoid tissue within the eye, that is collected for diagnostic disease testing, thus improving diagnostic efficiency of the test being conducted.

## **Summary of Invention**

.[] 1) Histamine containing eye drops are applied to the eye of an animal or person being tested, to visually identify lymphoid tissue within the area of the eye. The tissue is then sampled and submitted for further diagnostic testing.

- [] 2) Examples of diseases that could potentially be tested for using this include; Sheep = Scrapie, Deer and Elk = Chronic Wasting Disease (CWD), Human = Creutzfedt-Jakob Disease (CJD), Cattle = Bovine Spongiform Encephalopathy (BSE). These are only illustrated examples, as there may be many other diseases and species that this could be used to aid diagnostic testing.
- [] 3) Prior to the use of Histamine eye drops, it has been extremely difficult to identify lymphoid tissue in the eye. This limited the success of diagnostic tests that used lymphoid tissue from the eye. By using Histamine containing eye drops, the percentage of useful and diagnostic samples is often increased from ~40% to ~95%.
- [] 4) Provisional Application Number 60/466,943.

#### **Detailed Description**

- [] 1) Histamine eye drops are made by adding Histamine phosphate to an aqueous solution. This solution could be sterile water, 0.5% Proparacaine Hydrochloride Ophthalmic Solution (commercially available), or any other ophthalmic medications.
- [] 2) Histamine is added to make a final 1% Histamine containing solution. (10mg/ml).
- [] 3) Once the eye drops are prepared, the drops are then placed into the eye of the animal or person being tested. The lymphoid tissue within the eye can then be visually identified and specifically sampled (Biopsy) for further testing.
- [] 4) This visual identification is based upon the Histamine receptors in the lymphoid follicles of the eye, causing a localized vasodilatation of blood vessels. The lymphoid tissue contained within the eye area is then highlighted by the increase blood flow, causing a contrast difference changing the color of the lymphoid tissue from the non lymphoid tissue surrounding it.

  (See Attachment 1A).
- [] 5) Ideal sampling is done ~6 minutes after the application of the Histamine containing eye drops.
- The naturally occurring endogenous Histaminease contained within the eye then deactivates the externally applied Histamine, thus returning the lymphoid and non lymphoid tissues to their pre application condition.
- [] 7) The Histamine eye drops does not adversely affect the diagnostic test being used. In the attached example, the histamine did not affect TSE antigen staining or H & E Staining of a diagnostic lymphoid follicle. (See Attachment 1B)